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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/477,316 06/07/95 GRAY

J 028723-060

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EXAMINER

MARSCHEL, A

ART UNIT

PAPER NUMBER

1655

DATE MAILED:

11/29/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/477,316

Applicant

Gray et al.

Examiner

Ardin Marschel

Group Art Unit

1655



☒ Responsive to communication(s) filed on Aug 17, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1, 48, and 50-58 is/are pending in the application

~~Of the above, claim(s) 2-47 and 49 have been canceled.~~ ~~is/are withdrawn from consideration~~

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 48, and 50-58 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1655.

If an applications wishes to have priority benefit under § 120 to a parent application, specific reference to the parent application must be made in the instant application. It is noted that this appears as the first sentence of the specification following the title. Status of the parent application (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "Patent No." should follow the filing date of the parent application. If a parent application has become abandoned, the expression "abandoned" should follow the filing date of the parent application.

Applicants are hereby informed that the finality of the office action, mailed 3/17/99, is withdrawn due to the application of newly applied rejections as summarized below. The Reply, filed 8/17/99, have been entered.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Claims 1, 48, and 50-58 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

All of the independent claims such as claim 1, line 1, requires the staining of interphase chromosomal material. Lines

7-8 of claim 1, for example, in contrast includes the chromosomal material as being present in a morphologically identifiable chromosome. These two phrases conflict in that interphase chromosomal material does not contain morphologically identifiable chromosomes but rather are a diffuse nuclear state without condensed separately identifiable chromosomes. Thus, clarification of what target chromosomal material is meant to be analyzed in the instant claims via clearer claim language.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order

for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1, 48, and 50-58 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Weissman et al., taken in view of Lichter et al. and further in view of either of Le Beau et al. (for chromosome 17 targets) and Drabkin et al. (for chromosome 3 targets).

Weissman et al. as summarized of record discloses the preparation of large unique sequence probes sets for hybridization assay of various chromosomal aberrations including translocations. Motivation for assaying translocations is given in column 2, lines 13-39. The study of gene organization, of which translocations are clearly one type, are the subject of the Weissman et al. invention as noted in column 5, lines 53-58. Weissman et al., however, does not disclose interphase target assays nor specifically assaying directed to translocations in chromosomes 3 and/or 17.

Lichter et al. discloses interphase target assays for genetic abnormalities utilized in an hybridization assay format. Several chromosomal regions which are distinctly detectable in such interphase samples are described in the paragraph bridging the first and second columns on page 9664. This discription and the results in Lichter et al. give a reasonable expectation of success for such interphase assays, also as being equivalently

usable as metaphase target based assays.

Le Beau et al. in the abstract discloses chromosome 17 translocations as motivated targets regarding acute promyelocytic leukemia. This is motivation to assay for such translocation events.

Drabkin et al. in the abstract discloses a translocation involving chromosome 3 as being reported in a family with renal cell carcinoma. Other familial chromosome 3 translocations in the paracentromeric region is described in the paragraph bridging the first and second columns on page 6980. This is motivation to assay for such translocation events.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the instant invention because Weissman et al. generically suggests and motivates chromosomal abnormality hybridization assays with large unique probe sets. Lichter et al. describes hybridization assays utilizing interphase targets. Hybridization assays are generically utilized by Weissman et al. for the invention therein disclosed. Le Beau et al. and Drabkin et al. describe and motivate assay of chromosomes 17 and 3, respectively, as a target for hybridization assay due to translocations involving this chromosome. These disclosures together motivate and thus describe the instant invention.

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially

created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 48, and 50-58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 48-50 of application Serial No. 08/487,387; although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending applications contain common embodiments directed to high complexity probe methodology.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37

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Art Unit: 1655

CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

November 19, 1999


ARDIN H. MARSCHEL
PRIMARY EXAMINER